



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/463,097	01/18/00	ZIMMERMANN	J 4-30096/A

EXAMINER	
BERNHART, E.	

ART UNIT	PAPER NUMBER
1624	11

001095 HM12/0705
THOMAS HOXIE
NOVARTIS CORPORATION
PATENT AND TRADEMARK DEPT
564 MORRIS AVENUE
SUMMIT NJ 07901-1027

DATE MAILED: 07/05/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on 3/28/01
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-8, 10, 12-15 and 14 FB 10/22/01 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-8, 10, 12-15 and 16 is/are rejected. FB 10/22/01
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftperson's Patent Drawing Review, PTO-948
- ☐ of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Art Unit: 1624

In view of applicants response filed 3/28/01 the following still applies.

The abstract provided has been entered since no earlier abstract is seen in the file.

The claims pending are 1-8,10,12 and new 13-15. Applicants mention in their response that claim 10 was cancelled. This may have been an oversight since 10 is a composition claim. Perhaps applicants meant to say claim 11.

Claims 1-8,15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 4-8 are still not shown to materially differ from each other. The same also applies for 1vs 6 and new 15 vs 16. For 16 the same data appears as for claim 7. Applicants rely on additional characterization data but do not show how this data changes the

Art Unit: 1624

scope of these compound claims. Specification does not make any distinctions. Thus the urged differences in scope is still unclear.

2. Reason # 3 of the previous action remains. It is not seen how the same or overlapping reaction conditions can achieve simultaneously dissolution and digestion.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 14 which is directed to a method of treating any and all types of tumors (original claim 11 was directed to a method for making compositions for antitumor use) is not enabled based solely on the assay testing reported in the specification on p.10. Displaying in vitro PDGF inhibitory activity is not synonymous with successful treatment of all tumor-related diseases in man. Note In re Buting 163 USPQ 689 it

Art Unit: 1624

was decided that a showing for two types of cancer was not a sufficient showing for the list of tumors claimed. Broad-based anti-tumor agents are not well known in general.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-8,10,13-¹⁶15 are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmermann for reasons of record. *FB 10/22/01*

Claims 1-8,10,13-¹⁶15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmermann for reasons of record. *FB 10/22/01*

Claim 12 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmermann in view of Yu for reasons of record.

Applicants' traverse to the above rejections is not persuasive. The examiner is not obligated to rely on more broader disclosures when narrower ones are also present. Also it is not agreed that the salt forms are not particularly contemplated when in col. 3, lines 61-67 the following is stated: "Owing to the close relationship between the

Art Unit: 1624

novel compounds in free form and in the form of their salts....hereinbefore and hereinafter any reference to the free compounds should be understood as including the corresponding salts,where appropriate and expedient.” . It is well settled that the test for anticipation is not if a compound is actually made but if its preparation is within the knowledge of those of ordinary skill. See Ex parte A 17 USPQ 2d 1716 and the case law cited therein. In fact the court in Petering went on to say that even the corresponding isomers of the 20 preferred compounds would be considered anticipatory since the existence of these isomers would be well known to those of ordinary skill. See left column of p.280,last paragraph.Thus the naming of the free base coupled with the particular salts recited in col.3 constitutes an anticipation for each and every of recited salts which include the methanesulfonate salt. The burden is on applicants not the examiner to show that their particular salt form (the beta form) cannot be made following routine conditions. The case law cited by the

Art Unit: 1624

examiner supports this contention of who has the burden of proof.

Neither the Fitzgerald or Grose decisions have been addressed much less refuted by applicants. Also see In re Best 195 USPQ 430 which has the following quote " Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may, in fact, be an inherent characteristic in the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on."

As the product is not allowed the corresponding process remains rejected .

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1624

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Application/Control Number: 09/463097

Page 8

Art Unit: 1624

E Bernhardt
EMILY BERNHARDT
PRIMARY EXAMINER

Emily Bernhardt
EMILY BERNHARDT
PRIMARY EXAMINER